



Docket No.: 62041(51588)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
David Elmaleh, *et al.*

Application No.: 10/827,054

Confirmation No.: 2370

Filed: April 19, 2004

Art Unit: 1618

For: METHOD FOR MONITORING BLOOD FLOW
AND METABOLIC UPTAKE IN TISSUE WITH
RADIOLABELED ALKANOIC ACID

Examiner: M. J. Perreira

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants respectfully invite the attention of the Patent and Trademark Office to the references listed on the attached PTO/SB/08. Applicants respectfully request that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

A summary/abstract translation of the non-English language references is enclosed. With regard to reference DY (Schlosser, M., *et al.*, "Fluor-olefine durch Fluormethylenierung von Carbonylverbindungen" 1969, Synthesis 1: 75-76) we note that no English-Language translation or abstract is readily available at this time. Nevertheless, Applicants respectfully submit that this reference relates to methods of synthesizing vinyl fluoride compounds using a Wittig-type reaction as the Examiner can readily observe from the structures shown.

In accordance with 37 C.F.R. §1.98(a)(2)(ii), Applicants have not submitted copies of U.S. patents and U.S. patent applications. Applicants submit herewith copies of foreign patents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

In accordance with 37 C.F.R. §1.97(g), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(a) exists. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Supplemental Information Disclosure Statement is in compliance with 37 C.F.R. 1.98 and the Examiner is respectfully requested to consider the listed references.

This Supplemental Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits but before the mailing date of a Final Office Action or Notice of Allowance (37 C.F.R. 1.97(c)). However, this Supplemental Information Disclosure Statement is filed in response to an objection by the Examiner that the earlier filed Information Disclosure Statement failed to provide a legible copy of each foreign patent document or non-patent literature publication. Applicants respectfully disagree with this contention.

Although the electronic file history (via the PAIR system) shows that, sometime after submission, the IDS was stamped "Items not received: 37 NPL", Applicants respectfully submit that legible copies of all references listed in the original IDS were submitted and received by the USPTO. Evidence of this receipt is provided by the stamped return receipt postcard (a copy of which is submitted herewith) acknowledging receipt of all 150 references. Nevertheless, Applicants respectfully resubmit those references which the Examiner previously crossed out as not provided in this Supplemental Information Disclosure Statement.


Application No.: 10/827,054
SIDS

Attorney Docket No. 62041(51588)

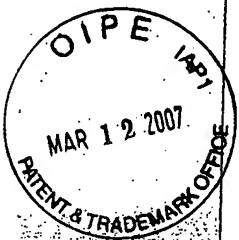
As each of these references had previously been submitted in a timely manner in the prior Information Disclosure Statement of record, Applicants submit that no additional fee should be charged for this SIDS. Nevertheless, should the Director determine that a fee is still required, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 62041(51588). A duplicate copy of this paper is enclosed.

Dated: March 12, 2007

Respectfully submitted,

By 
Nicholas DiCeglie, Jr.
Registration No.: 51,615

Peter C. Lauro, Esq.
Registration No. 32,360
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 439-4444
Attorneys/Agents For Applicants



Serial No. 10/827,054 File No. 910500-2042.1 By AK/LM
Title in the Matter of the Application of Method of Monitoring Blood Flow
Applicant(s)/Inventor(s) Elmaleh et al.
The following due _____ in the U.S. Patent Office, was received in the Patent Office
☐ Affidavit ☐ Declaration ☐ Express Mail Mailing Label # EUI96822666 US
☐ Amendment ☐ (separate sheet)
☐ Preliminary Amendment ☐ Check No. _____ for \$ _____
☐ Amendment After Final Rejection ☐ Deposit Account Order Form
☐ Request for Extension of Time ☐ Drawing _____ Sheet(s)
☐ Provisional Patent Application ☒ Information Disclosure Statement
☐ Application for Patent, including ☒ PTO Form 1449 4 150 Refs
_____ Pages Specification _____ Claims _____ Abstract
☐ Declaration ☐ Oath ☐ Power ☐ Issue Fee/Publication Fee Transmittal
☐ Request for Filing Continuation or Divisional ☐ Appeal Brief (triplicate) ☐ Letter
Application _____ sheets ☐ Application for TM Registration
Including _____ Specimens
☐ PCT Request _____ sheets, including ☐ Status Request ☐ Notice of Appeal (triplicate)
☐ Transmittal Letter ☐ Petition ☐ Response
☐ Request for Continued Exam (RCE) ☐ Priority Document
☐ Assignment ☐ Recordation Cover Sheet ☐ Statement of Use
☐ Amendment Fee Transmittal ☐ Response to Examiner's Statement
☐ Claim of Priority ☐ Search Report
☐ Request for Approval of Drawings ☐ Response to Notice to File Missing Parts
☐ Diskette with Sequence Listing

Mailed on: 8/4/04

Serial No. 10/827,054 File No. 910500-2042.1 By AK/LM
Title in the Matter of the Application of Method of Monitoring Blood Flow
Applicant(s)/Inventor(s) Elmaleh et al.
The following due _____ in the U.S. Patent Office, was received in the Patent Office
☐ Affidavit ☐ Declaration ☐ Express Mail Mailing Label # EUI96822666 US
☐ Amendment ☐ (separate sheet)
☐ Preliminary Amendment ☐ Check No. _____ for \$ _____
☐ Amendment After Final Rejection ☐ Deposit Account Order Form
☐ Request for Extension of Time ☐ Drawing _____ Sheet(s)
☐ Provisional Patent Application ☒ Information Disclosure Statement
☐ Application for Patent, including ☒ PTO Form 1449 4 150 Refs
_____ Pages Specification _____ Claims _____ Abstract
☐ Declaration ☐ Oath ☐ Power ☐ Issue Fee/Publication Fee Transmittal
☐ Request for Filing Continuation or Divisional ☐ Appeal Brief (triplicate) ☐ Letter
Application _____ sheets ☐ Application for TM Registration
Including _____ Specimens
☐ PCT Request _____ sheets, including ☐ Status Request ☐ Notice of Appeal (triplicate)
☐ Transmittal Letter ☐ Petition ☐ Response
☐ Request for Continued Exam (RCE) ☐ Priority Document
☐ Assignment ☐ Recordation Cover Sheet ☐ Statement of Use
☐ Amendment Fee Transmittal ☐ Response to Examiner's Statement
☐ Claim of Priority ☐ Search Report
☐ Request for Approval of Drawings ☐ Response to Notice to File Missing Parts
☐ Diskette with Sequence Listing

Mailed on: 8/4/04



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/827,054-Conf. #2370
				Filing Date	April 19, 2004
				First Named Inventor	David Elmaleh
				Art Unit	1618
				Examiner Name	M. J. Perreira
Sheet	1	of	3	Attorney Docket Number	62041(51588)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	BB	WO 2004/092184 A1	10/28/2004	Forschungszentrum Rossendorf E.V.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AE	AMBROSE et al., "Evaluation of the metabolism in rat hearts of two new radioiodinated 3-methyl-branched fatty acid myocardial imaging agents", Eur Jnl Nucl Med (1987), 12:486-491.	
	AF	AMBROSE et al., "Effect of 3-methyl-branching on the metabolism in rat hearts of radioiodinated iodovinyl long chain fatty acids", Eur Jnl Nucl Med (1987) 13:374-379.	
	AL	DE GEETER et al., "Relationship between blood flow and fatty acid metabolism in subacute myocardial infarction: a study by means of ^{99m} Tc-Sestamibi and ¹²³ I-β-methyl-iodo-phenyl pentadecanoic acid", Eur Jnl of Nucl Med, Vol. 21, No. 4, (1994).	
	AN	DEGRADO et al., "β-Methyl-15-p-iodophenylpentadecanoic acid metabolism and kinetics in the isolated rat heart", Eur Jnl Nucl Med (1989), 15:78-80.	
	AY	FRITZBERG et al., "Iodophenylsulfonamide fatty acid analogs as potential myocardial imaging agents", Int Jnl Appl Radiat Isot (1982) 33(6): 451-3.	
	AZ	FUJIBAYASHI et al., "Myocardial accumulation of iodinated beta-methyl-branched fatty acid analog, [125I](p-iodophenyl)-3-(R,S)-methylpentadecanoic acid (BMIPP), and correlation to ATP concentration - II, Studies in salt-induced hypertensive rats", Nucl Med Biol (1993) 20(2): 163-6.	
	BA	FUJIBAYASHI et al., "Basic Studies on I-123-beta-methyl-p-iodophenylpentadecanoic Acid (BMIPP) for Myocardial Functional Diagnosis: Effect of Beta-oxidation Inhibitor",	
	BH	HASEGAWA et al., "Detection of viable myocardium with p-iodophenyl-9-(R,S)-methylpentadecanoic acid in ischemic rat myocardium", Jnl of Nucl Cardiology, (2002) Vol. 9, 5:463-70.	
	BI	HASHIMOTO et al., "Prediction of left ventricular functional recovery in patients with acute myocardial infarction using single photon emission computed tomography with thallium-201 and iodine-123-beta-methyl-p-iodophenyl-pentadecanoic acid", Jnl Cardiology, (1995) 26(2): 59-68. PubMed English Abstract, 2-pages.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/827,054-Conf. #2370
				Filing Date	April 19, 2004
				First Named Inventor	David Elmaleh
				Art Unit	1618
				Examiner Name	M. J. Perreira
Sheet	2	of	3	Attorney Docket Number	62041(51588)

BQ	ISOBE et al., "The characteristics of myocardial fatty acid metabolism in patients with left ventricular hypertrophy", Kaku Igaku, (1999) 36(7): 725-33, PubMed English Abstract, 2-pages.
BR	ISOBE et al., "Usefulness of 201Tl/123I-BMIPP myocardial SPECT to evaluate myocardial viability and area at risk in acute myocardial infarction -comparison with 201Tl/99mTc-PYP dual SPECT", Kaku Igaku, (1997) 34(4): 213-20, PubMed English Abstract. 1 page.
BS	ITO et al., "Relation between thallium-201/iodine 123-BMIPP subtraction and fluorine 18 deoxyglucose polar maps in patients with hypertrophic cardiomyopathy", Jnl Nucl Cardiology, (2000), Vol. 7, 1;16-22.
BY	KAWAMOTO et al., "Value of fatty acid imaging using 123I-beta-methyl iodophenyl pentadecanoic acid (BMIPP) to assess viability of infarcted myocardium", Kaku Igaku, (1991), 28(9): 1081-9, PubMed English Abstract, 1 pages.
BZ	KAWAMURA et al., "Evaluation of Branched Chain Fatty Acid, BMIPP [β -methyl- ω -(p-iodophenyl)-pentadecanoic acid] for the Myocardial Imaging - basic experiment", Kaku Igaku (1992) 29(4): 453-61.
CB	KIHARA et al., "Clinical study on myocardial imaging with beta-methyl-p-(123I)-iodophenyl-pentadecanoic acid in patients with mitochondrial myopathy", Kaku Igaku, (1992), 29(4):453-61, PubMed English Abstract, 1 pages.
CC	KIM et al., "Detection of impaired fatty acid metabolism in right ventricular hypertrophy: Assessment by I-123 β -methyl iodophenyl pentadecanoic acid (BMIPP) myocardial single-photon emission computed tomography", Annals of Nucl Med, (1997) Vol. 11, 3, 207-212.
CG	KNAPP et al., "Iodine-123-labelled fatty acids for myocardial single-photon emission tomography: current status and future perspectives", Eur Jnl of Nucl Med, (1995) Vol., 22, No. 4, 361-381.
CH	KNAPP et al., "New radioiodinated methyl-branched fatty acids for cardiac studies", Eur Jnl of Nucl Med (1986), 12:S39-S44.
CI	KOBAYASHI et al., "Fatty acid metabolic and perfusion abnormalities in hypertrophied myocardium assessed by dual tracer tomography using thallium-201 and iodine-123-beta-methylpentadecanoic acid", Jnl Cardiology, (1994), 24(1): 35-43, PubMed English Abstract, 2 pages.
CR	MACHULLA et al., "Biochemical Concept and Synthesis of a Radioiodinated Phenylfatty Acid for in Vivo Metabolic Studies of the Myocardium", Eur Jnl Nucl Med, (1980), 5, 171-173.
CU	MORI et al., "Relationship between ventricular arrhythmias and myocardial fatty acid metabolism in patients with coronary heart disease: evaluation using iodine-123 beta-methyl-p-iodophenyl-pentadecanoic acid", Jnl of Cardiology, (1999), 34(2):61-9, PubMed English Abstract, 2 pages.
DA	NISHIMURA et al., "Prognosis of hypertrophic cardiomyopathy: Assessment by ¹²³ I-BMIPP (β -methyl-p-(¹²³ I)-iodophenyl pentadecanoic acid) myocardial single photon emission computed tomography", Annals of Nucl Med, Vol. 10, No. 1, (1996) 71-78.
DC	NISHIMURA et al., "Fatty acid myocardial imaging using ¹²³ I- β -methyl-iodophenyl pentadecanoic acid (BMIPP): comparison of myocardial perfusion and fatty acid utilization in canine myocardial infarction (Occlusion and reperfusion model), Eur Jnl Nucl Med (1989) 15:341-345.
DE	NISHIMURA et al., "Clinical results with β -methyl-p-(¹²³ I)iodophenylpentadecanoic acid, single-photon emission computed tomography in cardiac disease", Jnl of Nucl Cardiology, (1994) Vol. 1, No. 2:S65-S71.
DR	SCHELBERT, H.R., "Positron-emission tomography: assessment of myocardial blood flow and metabolism", Circulation (1985), Vol. 72 (suppl IV), IV-122 - 133.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/827,054-Conf. #2370
				Filing Date	April 19, 2004
				First Named Inventor	David Elmaleh
				Art Unit	1618
				Examiner Name	M. J. Perreira
Sheet	3	of	3	Attorney Docket Number	62041(51588)

	DY	SCHLOSSER et al., "Fluor-olefine durch Fluormethylenierung von Carbonylverbindungen", Synthesis, 1:75-76	
	DZ	SCHON, et al., "C-11 labeled palmitic acid for the noninvasive evaluation of regional myocardial fatty acid metabolism with positron computed tomography. II. Kinetics of C-11 palmitic acid in acutely ischemic myocardium", 1982, Am Heart Jnl 103:548-561.	
	EB	SHIOTANI et al., "Myocardial SPECT with iodine-123-labeled beta-methyl-branched fatty acid in patients with angina pectoris", Kaku Igaku, (1994), 31(11):1343-9, PubMed English Abstract, 1 page.	
	EC	SHOGASE et al., "A role of nuclear medicine in diagnosing cardiac disease - clinical use of 123I-BMIPP and 123I-MIBG", Rinsho Byori (2000), 48(2):113-20, PubMed English Abstract, 1 page.	
	EM	TAKAHASHI et al., "Clinical usefulness of myocardial iodine-123-15-(p-iodophenyl)-3(R,S)-methyl-pentadecanoic acid distribution abnormality in patients with mitochondrial encephalomyopathy based on normal data file in bull's-eye polar map", Jnl. of Cardiology, (1998), 31(1):1-10, PubMed English Abstract, 1 page.	
	EN	TAMAKI et al., "Myocardial imaging using PET and SPECT", Nippon Rinsho (1998), 56(10):2550-5, PubMed English Abstract, 1 page.	
	EO	TAMAKI et al., "Radionuclide assessment of myocardial fatty acid metabolism by PET and SPECT", Jnl of Nucl Cardiology (1995) 2:256-66.	
	EQ	TANIGUCHI et al., "Separate evaluation of beta-methyl fatty acid uptake and perfusion in rat myocardium", Kaku Igaku, (1989) 26(12):1523-30, PubMed English Abstract, 1 page.	
	EW	WESTERA et al., "A Comparison Between Terminally Radioiodinated Hexadecenoic Acid (¹²⁵ I-HA) and ²⁰¹ Tl-Thallium Chloride in the Dog Heart", Eur Jnl Nucl Med, (1980), 5, 339-343.	
	FK	CORBETT. J.R., "Fatty Acids for Myocardial Imaging", [Cardiovascular Nuclear Medicine, Part 1], Seminars in Nuclear Medicine, Vol. XXIX, No. 3 (1999) pp. 237-258.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--